PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61B 5/0205, 5/08 // 5/02

(11) International Publication Number:

WO 99/08589

A1

FI

(43) International Publication Date:

25 February 1999 (25.02.99)

(21) International Application Number:

PCT/FI98/00640

(22) International Filing Date:

19 August 1998 (19.08.98)

(30) Priority Data:

973424

20 August 1997 (20.08.97)

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT,

(81) Designated States: JP, US, European patent (AT, BE, CH, CY,

In English translation (filed in Finnish).

(71) Applicant (for all designated States except US): INSTRU-MENTARIUM OY [FI/FI]; Teollisuuskatu 27, FIN-00510 Helsinki (FI).

(72) Inventor; and

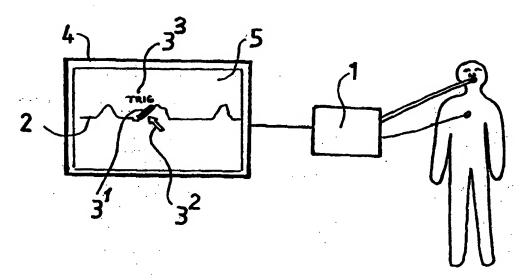
(75) Inventor/Applicant (for US only): HÄGGBLOM, Tom [FI/FI]; Minkkitie 10 B 19, FIN-01450 Vantaa (FI).

(74) Agent: PAPULA REIN LAHTELA OY; Fredrikinkatu 61 A, P.O. Box 981, FIN-00101 Helsinki (FI).

(54) Title: METHOD AND SYSTEM IN CONNECTION WITH PATIENT MONITORING

(57) Abstract

The invention relates to a procedure in conjunction with patient monitoring, in which a medical action performed by an appliance is controlled by means of a physiological parameter measured from the patient. A limit value is set for a parameter signal corresponding to the physiological parameter for the patient. The parameter signal is measured from the patient. The measured parameter signal is indicated in the form of a graphic representation. The medical action is triggered when the measured parameter signal



has reached the preset limit value or when it is anticipated that the limit value will be reached. The triggering of the action and/or the operativeness of the action is/are indicated. The indication of the triggering and/or operativeness of the action is combined with the graphic representation of the triggering parameter signal and/or a parameter signal logically related to it.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	A Disanta	200						•
AL	Albania	ES	Spain	٠.	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland		LT	Lithuania	SK	Slovakia
AT	Austria	FR	France		LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon		LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom		MC	Monaco	TD	Chad
BĄ	Bosnia and Herzegovina	GE	Georgia		MD ·	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana		MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea		MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		•	Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary		ML	Mali	TT	Trinidad and Tobago
BJ.	Benin	IE	Ireland		MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel		MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland		MW	Malawi	us	United States of America
CA	Canada	IT	Italy		MX	Mexico	UZ	Uzbekistan .
CF.	Central African Republic	JP	Japan		NE	Niger	VN .	Vict Nam
CG	Congo	KE	Kenya		NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan		NO	Norway	zw	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's		NZ	New Zealand	211	Zimbaowe
CM	Cameroon		Republic of Korea		PL	Poland		•
CN	China	KR	Republic of Korea		PT	Portugal		
CU	Cuba	KZ	Kazakstan		RO	Romania		_
CZ	Czech Republic	LC	Saint Lucia		RU	Russian Federation		•
DE	Germany	LI	Liechtenstein		SD	Sudan		
DK	Denmark	LK	Sri Lanka		SE	Sweden		
EE	Estonia	LR	Liberia		SG	Singapore		

10

15

20

25

30

METHOD AND SYSTEM IN CONNECTION WITH PATIENT MONITORING

The present invention relates to a procedure as defined in the preamble of claim 1. Moreover, the invention relates to a system as defined in the preamble of claim 7.

It is known in prior art that active medical appliances, such as respirators and/or drug administrating devices, can be controlled by means of a physiological parameter measured from the patient so that an assisting or curative process is automatically triggered into action as soon as the physiological parameter signal has reached a preset limit. Usually, the user interface, which displays the parameter signal as a graphic representation, comprises some kind of means by which the user may recognise that a process has been triggered. Such means may consist of e.g. sound, light or displayed text. A problem with prior-art methods and systems is that the indication of a triggered action is presented completely separately from the triggering physiological signal, which means that it is difficult for the user to recognise the relation between the physiological signal and the action triggered, i.e. to determine the physiological occurrence that caused the triggering and the effect produced by the action on the physiological signal.

The object of the present invention is to eliminate the drawbacks mentioned above.

A further object of the invention is to disclose a procedure and a system that make it easier to establish a logical connection between mutually related physiological occurrences and medical actions triggered.

The procedure of the invention is characte-5 rised by what is presented in claim 1. The system of the invention is characterised by what is presented in claim 7. WO 99/08589 2 PCT/FI98/00640

In the procedure of the invention, a limit value is set for a parameter signal corresponding to a physiological parameter for a patient. The limit value can be set by the user of the appliance or the appliance may change the limit value or set new limit values independently. The limit value may concern an upper limit and/or a lower limit, depending on the parameter to be measured. The parameter signal is then measured from the patient, the measured parameter signal is indicated in the form of a graphic representation, a medical action is triggered when the measured parameter signal has reached a preset limit value or when it is anticipated that the limit value will be reached. After this, the triggering of the action and/or the operativeness of the action is/are indicated.

According to the invention, the indication of the triggering and/or operativeness of the action is combined with the graphic representation of the triggering parameter signal and/or a parameter signal logically related to it. In this way, the user can clearly recognise the physiological occurrence that caused the triggering as well as the effect of the triggered action on the parameter signal. The triggering could also be indicated in signals that are somehow related to the triggering signal.

In an embodiment of the procedure, the triggering and/or operativeness of the action is/are indicated in the graphic representation of the parameter signal as a change of colour, tonal value, line width, line type or the like, as a pointer in the immediate vicinity of the graphic representation and/or as a text in the immediate vicinity of the graphic representation.

In an embodiment of the procedure, a display device and a user interface on the display of the display device are provided and the graphic representation of the parameter signal as well as the triggering

10

15

20

25

30

3 WO 99/08589 PCT/F198/00640

and/or operativeness are presented in the user interface.

In an embodiment of the procedure, the limit value of a limit parameter signal is varied via the user interface.

In an embodiment of the procedure, the operation of a respirator assisting the patient's respiration or maintaining it artificially or the administration of a medicament into the patient's respiratory passages 10 is controlled, for which purpose a limit value is set for a parameter signal corresponding to the respiratory duct pressure, flow and/or volume, the respiratory duct pressure, flow and/or volume are measured, the respiratory duct pressure, flow and/or volume are indicated in 15 the form of a graph, respiratory assistance and/or administration of medicine into the patient's respiratory ducts is/are triggered into action after the measured respiratory duct pressure, flow and/or volume has reached the set limit, and the triggering and/or operativeness is indicated in conjunction with the graph representing the respiratory duct pressure, flow and/or volume.

In an embodiment of the procedure, the medical action performed by the appliance consists of assisting heart activity, and the graphic representation of the measured parameter signal is an electrocardiogram.

In the system of the invention, the system comprises means for setting a limit value for a parameter signal corresponding to a physiological parameter for a patient; means for measuring the parameter signal from the patient; means for indicating the measured parameter signal in the form of a graphic representation; means for triggering a medical action after the measured parameter signal has reached the set limit or when it is anticipated that the limit will be reached; and means for indicating the triggering and/or operativeness of the medical process.

20

30

35

25

30

35

According to the invention, the means for indicating the triggering and/or operativeness of the action are combined with the graphic representation of the triggering parameter signal and/or a parameter signal logically related to it.

In an embodiment of the system, the system comprises a display device, which is provided with a user interface for the system, said user interface being so designed as to allow said limit value to be set, and which serves to display the graphic representation of the parameter signal and the triggering and/or operativeness of the action.

In an embodiment of the system, the means for indicating the triggering and/or operativeness of the action consist of changes in colour, tonal value, line width, line type or the like in the graphic representation of the parameter signal, and a pointer and/or a text in its immediate vicinity.

In an embodiment of the system, the graphic representation is a graph or the like.

In an embodiment of the system, the appliance is a respirator that assists the patient's respiration and/or maintains it artificially and/or a device for the dosage of medicine into the patient's respiratory ducts. In this case, the parameter signal to be measured is a parameter signal corresponding to respiration pressure, flow and/or volume.

In an embodiment of the system, the appliance is a device that assists heart activity. In this case, the graphic representation of the measured parameter signal is an electrocardiogram.

In the following, the invention will be described in detail by the aid of a few examples of its embodiments by referring to the attached drawings, wherein

Fig. 1 presents a diagram representing an embodiment of the system of the invention,

Fig. 2 presents a display of a graphic user interface comprised in an embodiment of the system of the invention,

Fig. 3 a second display of the user interface of the system with a control window opened,

Fig. 4 presents a third display of the user interface of the system with a control window opened,

Fig. 5 presents a fourth display of the user interface of the system.

10 Fig. 1 is a simplified diagram of a system for use in conjunction with patient monitoring. The medical action performed by the appliance 1 is controlled by means of a physiological parameter measured from the patient. The system comprises means for setting a limit value for a parameter signal corresponding to the phy-15 siological parameter for the patient. Moreover, system comprises means for measuring a parameter signal from the patient. Furthermore, the system comprises means for indicating a parameter signal in the form of a graphic representation 2. In addition, the system com-20 prises means for triggering a medical action after the measured parameter signal has reached the set limit value. The means 3^1 , 3^2 , 3^3 for indicating the triggering are directly incorporated in the graphic representation 2 of the triggering parameter signal or a parameter 25 signal logically related to it. A graphic user interface 5 is provided in the display of a display device 4. The user interface 5 is used to set the limit value and to present the graphic representation 2 and the means 30 for 3^1 , 3^2 , 3^3 indicating the triggering of the action.

The means for 3^1 , 3^2 , 3^3 indicating the triggering of the curative action or the like carried out by the appliance 1 consist of changes 3^1 in colour, tonal value, line width, line type or the like in the graphic representation 2 of the parameter signal, a pointer 3^2 and/or a text 3^3 appearing in its immediate vicinity.

10

Fig. 1 shows all these together, but they can also be used separately or in suitable combinations.

The appliance 1 may also consist of a respirator assisting and/or artificially maintaining the patient's respiration, and/or a device for the dosage of medicine into the patient's respiratory ducts. In this case, the parameter signal measured from the patient is a parameter signal corresponding to the respiratory duct pressure, flow and/or volume. The appliance 1 may also be a device assisting heart activity. In this case, the graphic representation of the measured parameter signal is an electrocardiogram.

Fig. 2 presents a graphic user interface 5 in which the topmost curve 2 represents a respiratory duct pressure measured from the patient, showing it as a 15 function of time. The curve p_{circ} 2 for the respiratory duct pressure is presented here for a period of one minute. In this case, the action to be controlled is inspiration by respirator, assisting the patient's own inspiration. The triggering of the assisting inspirati-20 on is based on the fact that, at the beginning of the patient's own inspiration, the respiration pressure falls below a preset limit. The assisting inspiration is of predetermined duration and volume. The triggering 25 as well as the operativeness and duration of the action are indicated in Fig. 2 by a wider black line 3^1 on an ascending part of the curve, representing the active inspiration stage when gas is flowing in. The triggering and duration can also be displayed in any other suitable manner that distinguishes this portion from 30 the normal pressure curve. The essential point is that that the indication of triggering is displayed in intermediate conjunction with the graph representing the triggering respiration pressure or other physiological parameter logically related to it and is clearly dis-35 tinguishable and readily intelligible to the user.

25

Fig. 3 and 4 illustrate the manner in which the respirator operation regarding its triggering into action is adjusted via control windows that can be opened in the user interface. The control window designated as "Trigger window" presents the respiratory duct pressure P[cmH2O] as a function of time t[s]. The width of the trigger window shown in the figure is adjustable. If the patient's respiratory duct pressure p during respiration falls to a value within the trigger 10 window, this will trigger the respirator into action to assist the patient's respiration. Fig. 4 illustrates a method for adjusting the triggering sensitivity. The control window 8 designated as "Sensitivity" presents the same graph as in Fig. 3, but in this case the trig-15 ger window 9 can be adjusted in the vertical direction, in other words, the limit pressure value at which triggering occurs can be adjusted.

Fig. 5 shows a "Spirometry" display window, representing flow volume spirometry, which means measuring the respiration volume, shown as Vol[m] on the horizontal axis, in relation to the respiration flow, shown as Flow[1/min] on the vertical axis. The action to be triggered is administration of medicine into the respiratory ducts. The extra wide line portion 3¹ of the curve represents the triggering of dosage of the medicine. It can be seen from the figure that the medicine is administered to the patient when the respiration volume is between 150 - 300 ml.

The invention is not restricted to the 30 examples of its embodiments described above, but many variations are possible within the scope of the inventive idea defined by the claims.

CLAIMS

- 1. Procedure in conjunction with patient monitoring, e.g. for use in anaesthesia and/or intensive care, in which a medical action performed by an appliance is controlled by means of a physiological parameter measured from the patient, and in which procedure
- a limit value is set for a parameter signal corresponding to the physiological parameter for the patient,
- the parameter signal is measured from the patient,

the measured parameter signal is indicated in the form of a graphic representation,

the medical action is triggered when the measured parameter signal has reached the preset limit value or when it is anticipated that the limit value will
be reached, and

the triggering of the action and/or the operativeness of the action is/are indicated,

- characterised in that the indication of the triggering and/or operativeness of the action is combined with the graphic representation of the triggering parameter signal and/or a parameter signal logically related to it.
- 2. Procedure as defined in claim 1, characterised in that the triggering and/or operativeness of the action is/are indicated in the graphic representation of the parameter signal as a change of colour, tonal value, line width, line type or the like, as a pointer in the immediate vicinity of the graphic representation and/or as a text in the immediate vicinity of the graphic representation.
- 3. Procedure as defined in claim 1 or 2, characterised in that a display device and a user interface on the display of the display device are provided and the graphic representation of the parame-

. 10

15

20

ter signal as well as the triggering and/or its operativeness are presented in the user interface.

- 4. Procedure as defined in claim 3, characterised in that the limit value of a limit parameter signal is varied via the user interface.
- 5. Procedure as defined in any one of claims 1 characterised in that the operation of a respirator assisting the patient's respiration and/or maintaining it artificially and/or the administration of medicine into the patient's respiratory ducts is/are controlled, for which purpose a limit value is set for parameter signal corresponding to the respiratory duct pressure, flow and/or volume; the respiratory duct pressure, flow and/or volume are measured; the respiratory duct pressure, flow and/or volume are indicated in the form of a graph; respiratory assistance and/or administration of medicine into the patient's respiratory ducts is/are triggered into action after the measured respiratory duct pressure, flow and/or volume reached the set limit, and the triggering and/or operativeness is/are indicated in conjunction with the graph representing the respiratory duct pressure, flow and/or volume.
- 6. Procedure as defined in any one of claims 1
 25 5, characterised in that the medical action performed by the appliance consists of assisting heart activity, and the graphic representation of the measured parameter signal is an electrocardiogram.
- 7. System in conjunction with patient monito30 ring, e.g. for use in anaesthesia and/or intensive care, in which a medical action performed by an appliance
 (1) is controlled by means of a physiological parameter
 measured from the patient, and which system comprises
- means for setting a limit value for a para-35 meter signal corresponding to the physiological parameter for the patient,

- means for measuring the parameter signal from the patient,
- means for indicating the measured parameter signal in the form of a graphic representation (2),
- means for triggering a medical action after the measured parameter signal has reached the set limit or when it is anticipated that the limit will be reached, and
- means (3¹, 3², 3³) for indicating the triggering and/or operativeness of the medical action.
 - characterised in that the means $(3^1, 3^2, 3^3)$ for indicating the triggering and/or operativeness of the action are combined with the graphic representation of the triggering parameter signal and/or a parameter signal logically related to it.
- 8. System as defined in claim 7, characterised in that the system comprises a display device (4), which is provided with a software based graphic user interface (5) to permit setting of the limit value and display of the graphic representation of the parameter signal and/or the means (3¹, 3², 3³) for indicating the triggering and/or operativeness of the action.
- 9. System as defined in claim 7 or 8, 25 characterized in that the means (3¹, 3², 3³) for indicating the triggering and/or operativeness of the action consist of changes in colour, tonal value, line width, line type or the like (3¹) in the graphic representation (2) of the parameter signal, a pointer 30 (3²) and/or a text (3³) in its immediate vicinity.
 - 10. System as defined in any one of claims 7 9, characterised in that the graphic representation (2) is a graph or the like.
- 11. System as defined in any one of claims 7 35 10, characterised in that the appliance (1) is a respirator that assists the patient's respiration and/or maintains it artificially and/or a device for

the dosage of a medicament into the patient's respiratory ducts; and that the parameter signal to be measured is a parameter signal corresponding to respiration pressure, flow and/or volume.

12. System as defined in any one of claims 7 - 10, characterized in that the appliance (1) is a device assisting heart activity; and that the graphic representation of the measured parameter signal is an electrocardiogram.

1/5

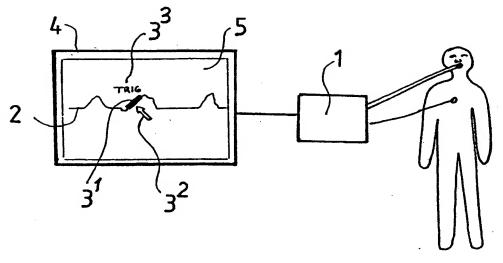
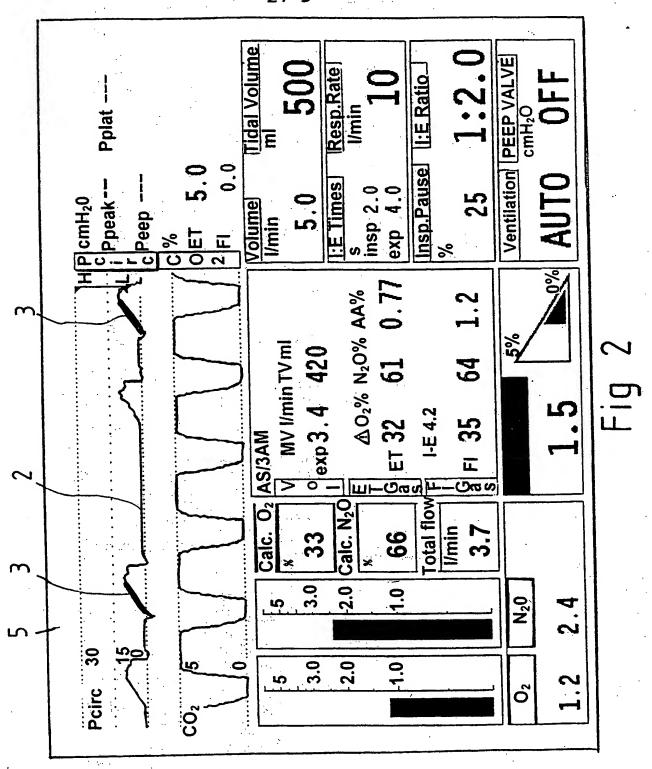
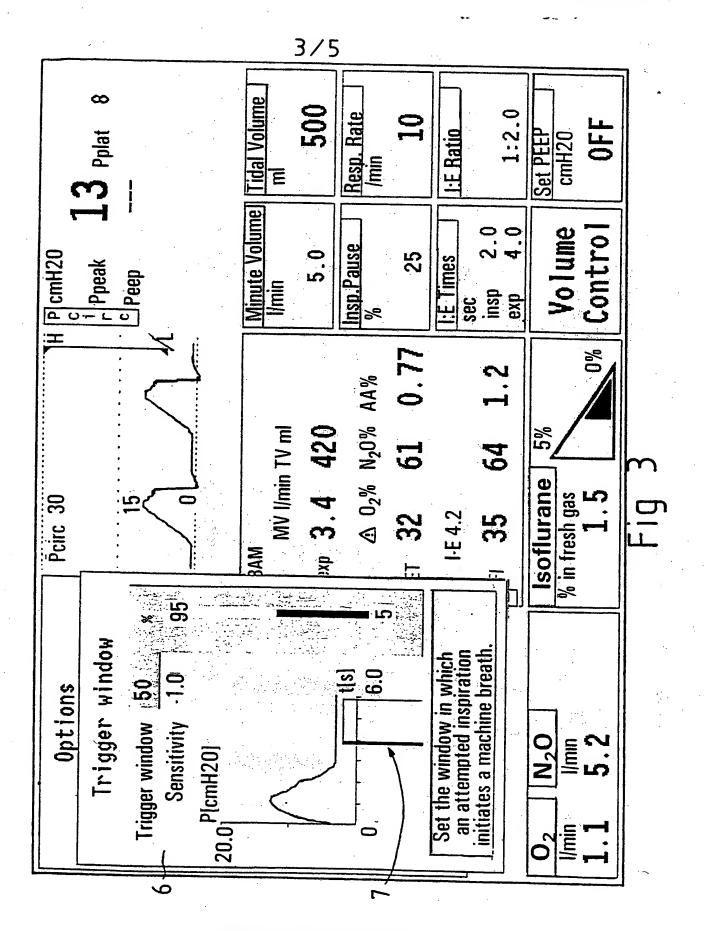
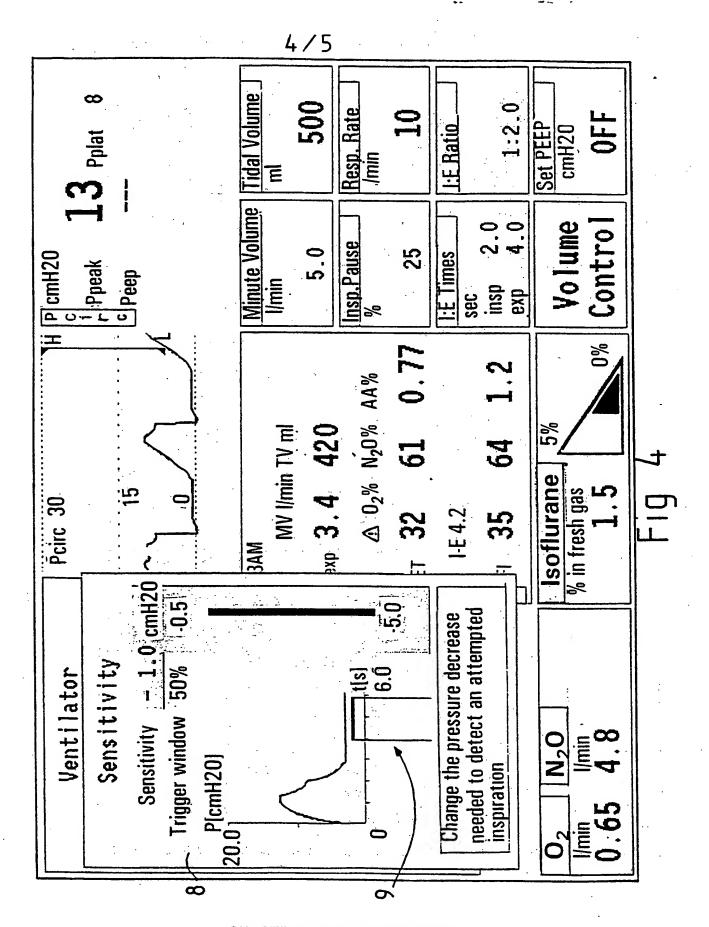


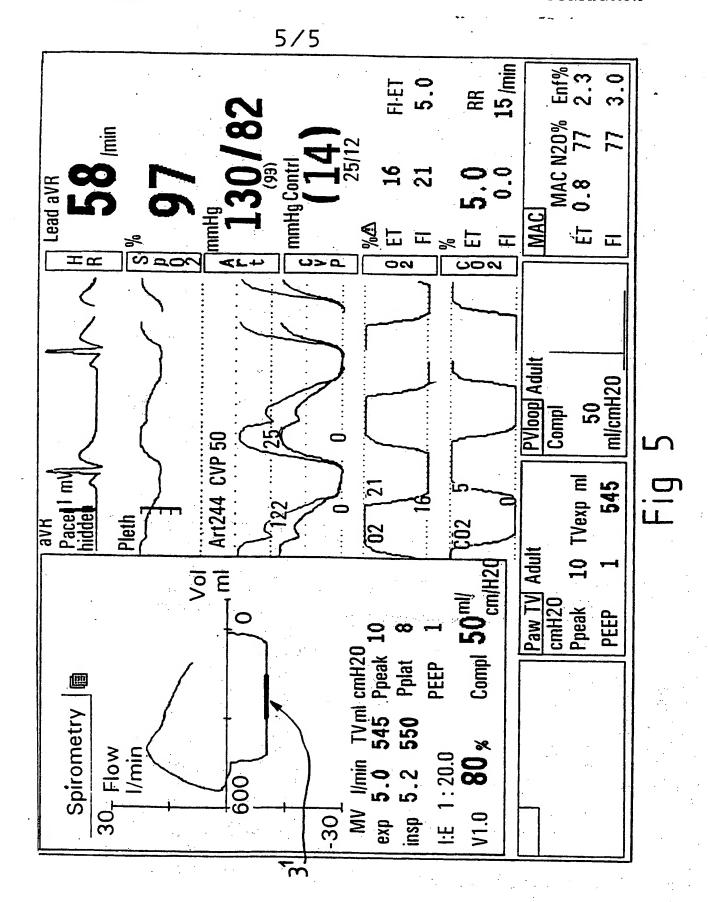
Fig 1







SUBSTITUTE SHEET (RULE 26)



INTERNATIONAL SEARCH REPORT

International application No. PCT/FI 98/00640

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/0205, A61B 5/08 // A 61 B 5/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61M, G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
P,X	WO 9817171 A1 (ALBERT EINSTEIN HEALTHCARE NETWORK), 30 April 1998 (30.04.98), page 4, line 21 - page 6, line 32	1-12			
		·			
Х	WO 9103979 A1 (WESTENSKOW, DWAYNE ET AL.), 4 April 1991 (04.04.91), page 6, line 3 - page 8, line 2, abstract	1-12			
					
X	US 5140519 A (WOLFGANG FRIESDORF ET AL.), 18 August 1992 (18.08.92), column 1, line 41 - column 2, line 4, figures 2,3, abstract	1-12			
		,			
		·			

X ruther documents are listed in	the continuation of Box C.	X See patent family annex.		
 Special categories of cited documents: "A" document defining the general state of the to be of particular relevance 	T" e art which is not considered	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention		
"E" erlier document but published on or after document which may throw doubts on projected to establish the publication date of special reason (as specified) document referring to an oral disclosure, means "P" document published prior to the international disclosure of the priority date claimed	nority claim(s) or which is another citation or other "Y" use, exhibition or other	considered novel or cannot be considered to involve an inventive step when the document is taken alone document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art		
Date of the actual completion of the 22 January 1999	international search Date	Date of mailing of the international search report 2 7 -01- 1999		
Name and mailing address of the ISA Swedish Patent Office Box 5055, S-102 42 STOCKHOL Facsimile No. + 46 8 666 02 86	M Jor	Authorized officer Joni Sayeler Telephone No. +46 8 782 25 00		

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 98/00640

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No	
X	US 5464012 A (RONALD FALCONE), 7 November 1995 (07.11.95), column 2, line 3 - line 40, abstract		
A	US 5002060 A (DROR NEDIVI), 26 March 1991 (26.03.91), see the whole document	1-12	
		•	

INTERNATIONAL SEARCH REPORT

Information on patent family members

01/12/98

International application No.
PCT/FI 98/00640

Patent document cited in search report		Publication date		Patent family member(s)	Publication date	
WO	9817171	A1	30/04/98	AU	4993397 A	15/05/98
WO	9103979	A1	04/04/91	AU CA EP JP US	6533290 A 2066756 A 0493525 A 5502388 T 5339818 A	18/04/91 21/03/91 08/07/92 28/04/93 23/08/94
US	5140519	A	18/08/92	DE EP JP	3817052 A 0343405 A 2057233 A	30/11/89 29/11/89 27/02/90
US	5464012	A	07/11/95	DE GB GB	4417574 A,C 2281781 A,B 9418355 D	16/03/95 15/03/95 00/00/00
US	5002060	Α	26/03/91	NONE		******

T .	1.754	Sign and Sig
No same		
		wa kaji
		- ×
	* * * * * * * * * * * * * * * * * * * *	
		· ·
	tive .	
	0	
	•	
		V ₁ U
· ·		
	<i>'</i> **	